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Evaluation of Serum Procalcitonin Levels for Antibiotic Stewardship in Respiratory Tract Infections

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Abstract: ***Background:*** Antibiotic resistance poses a significant global health challenge, particularly in respiratory tract infections (RTIs) where distinguishing between bacterial and viral etiologies remains crucial. This study evaluated serum procalcitonin (PCT) as a biomarker for guiding antibiotic stewardship in RTIs.

Methods: A 12-month prospective, observational study was conducted in a tertiary care hospital, enrolling 450 patients (225 per group) with various RTIs. PCT levels were measured using electrochemiluminescence immunoassay, with predefined cutoff values guiding antibiotic decisions. Outcomes were compared between PCT-guided and standard therapy groups.

Results: PCT demonstrated strong diagnostic utility with distinct thresholds: low levels (<0.1 µg/L) showed 86.5% negative predictive value for bacterial infection, while high levels (>0.5 µg/L) correlated strongly with bacterial etiology (91.4%). PCT-guided therapy reduced antibiotic duration significantly across all RTI types (mean reduction: CAP 2.9 days, AECOPD 2.9 days, upper RTI 3.1 days; $p<0.001$) while maintaining comparable clinical cure rates (PCT-guided: 89.3% vs. Standard: 88.0%, $p=0.65$). Protocol compliance improved from 82.3% to 91.8% over the study period.

Conclusion: PCT-guided antibiotic therapy demonstrated effectiveness in reducing antibiotic exposure while maintaining clinical outcomes across different RTI types. The clear correlation between PCT levels and bacterial infection provides a reliable framework for antimicrobial stewardship decisions, though clinical correlation remains essential, particularly in intermediate PCT ranges.

Keywords: Antibiotic stewardship, Bacterial infection, Procalcitonin, Respiratory tract infection, Serum biomarker.

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INTRODUCTION

Antibiotic resistance represents one of the most significant global health challenges of the 21st century, largely driven by the inappropriate and excessive use of antimicrobial agents (Smith et al., 2019). In respiratory tract infections (RTIs), distinguishing between bacterial and viral etiologies remains a crucial clinical challenge, often leading to unnecessary antibiotic prescriptions (Johnson & Peters, 2020). Procalcitonin (PCT), a precursor of calcitonin, has emerged as a promising biomarker for guiding antibiotic therapy decisions, particularly in respiratory infections (Williams et al., 2018).

Procalcitonin levels typically remain low in viral infections and non-infectious inflammatory conditions but rise significantly in bacterial infections, making it a valuable tool for antimicrobial stewardship programs (Thompson et al., 2021). The diagnostic and prognostic utility of PCT has been extensively studied in various clinical settings, with particular emphasis on respiratory tract infections due to their high prevalence and significant contribution to antibiotic consumption (Anderson et al., 2020).

Recent meta-analyses have demonstrated that PCT-guided therapy can reduce antibiotic exposure without compromising patient outcomes (Roberts et al., 2021). Studies have shown that implementing PCT-based algorithms can decrease antibiotic prescription rates by 40-60% in patients with respiratory tract infections while maintaining similar clinical outcomes compared to standard care (Davidson et al., 2019). The economic implications are also significant, with PCT-guided therapy showing potential cost savings through reduced antibiotic use and shorter hospital stays (Martinez et al., 2020).

The role of PCT in different respiratory tract infections varies, showing particular promise in community-acquired pneumonia (CAP) and acute exacerbations of chronic obstructive pulmonary disease (AECOPD) (Wilson et al., 2018). Research has indicated that PCT levels correlate well with disease severity and can predict bacterial infection with higher accuracy compared to traditional markers like C-reactive protein (CRP) and white blood cell count (Garcia et al., 2019).

However, the implementation of PCT-guided antibiotic stewardship faces several challenges, including standardization of cutoff values, timing of measurements, and integration into existing clinical protocols (Brown et al., 2020). The cost-effectiveness of PCT testing in different healthcare settings and patient populations remains an area of active research (Lee et al., 2021). Additionally, the impact of PCT-guided therapy on long-term outcomes and antimicrobial resistance patterns requires further investigation (Henderson et al., 2019).

Recent technological advances have improved the accessibility and turnaround time of PCT testing, making it more feasible for routine clinical use (Taylor et al., 2020). The development of point-of-care testing platforms has particularly enhanced the potential for PCT implementation in outpatient settings, where most antibiotic prescriptions occur (Phillips et al., 2021).

The study aimed to evaluate the effectiveness of serum procalcitonin-guided antibiotic therapy in patients with respiratory tract infections and its impact on antibiotic consumption, clinical outcomes, and healthcare costs. The objectives included assessing the correlation between PCT levels and bacterial infection, determining optimal cutoff values for antibiotic initiation and discontinuation, and analyzing the cost-effectiveness of PCT-guided therapy compared to standard care in different clinical settings.

MATERIALS & METHODS

***Study Design and site*:** This prospective, observational study was conducted at tertiary care hospital. The study followed patients admitted with respiratory tract infections over 06 months, comparing outcomes between PCT-guided and standard therapy groups.

***Sampling and Sample Size*:** The study employed stratified random sampling to recruit 450 patients (225 per group) based on power analysis (α=0.05, β=0.20). Sample size calculation considered previous studies showing a 40% reduction in antibiotic use with PCT guidance. Patient recruitment occurred in the emergency department and inpatient units.

Inclusion and Exclusion Criteria

***Inclusion Criteria*:**

Adults aged ≥18 years with clinical signs of respiratory tract infection
Radiologically confirmed pneumonia or clinical diagnosis of upper respiratory tract infection
Admission through emergency department or outpatient clinic
Consent to participate in the study

***Exclusion Criteria*:**

Severe immunosuppression or neutropenia
Active tuberculosis or fungal infection

- Pregnancy or lactation
- Prior antibiotic therapy within 48 hours
- Severe organ dysfunction or septic shock

Test Methodology: Serum PCT levels were measured using electrochemiluminescence immunoassay on Roche Cobas e411 analyzers. Samples were collected at admission and every 48 hours thereafter. PCT-guided therapy followed a predefined algorithm with cutoff values for antibiotic initiation (≥0.25 μg/L) and discontinuation (<0.25 μg/L or 80% decrease from peak).

Statistical Analysis: Data analysis was performed using SPSS version 25.0. Continuous variables were compared using Student's t-test or Mann-Whitney U test, and categorical variables using Chi-square or Fisher's exact test. Multivariate regression analysis assessed factors affecting antibiotic use and outcomes. P-values <0.05 were considered significant.

Ethical Considerations: The study received approval from institutional ethics committees of participating hospitals. Written informed consent was obtained from all participants. Data confidentiality was maintained throughout the study, and participants could withdraw at any time without affecting their care.

RESULTS

The demographic and clinical characteristics analysis of the study population (N=450) showed comparable baseline characteristics between the PCT-guided and standard care groups Table 1. The mean age was similar (58.4 ± 15.2 vs 57.9 ± 14.8 years, p=0.72), with a balanced gender distribution (56.9% vs 58.7% males, p=0.69). The distribution of RTI types was well-matched between groups, with Community-Acquired Pneumonia (CAP) being most common (43.6% vs 42.2%), followed by Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD) (33.8% vs 35.1%), and Upper RTI (22.6% vs 22.7%). Comorbidity profiles were also similar, including diabetes (29.8% vs 28.4%), hypertension (39.6% vs 40.9%), and heart disease (20.0% vs 21.3%). Clinical severity measures showed comparable distributions, with CURB-65 scores ≥3 (18.7% vs 19.6%) and qSOFA scores ≥2 (16.9% vs 16.0%). The PCT level distribution analysis revealed a strong correlation between PCT levels and infection types showed in Table 2. In patients with PCT <0.1 μg/L (n=89), only 13.5% had confirmed bacterial infections, while 76.4% had viral infections. The intermediate range of 0.1-0.25 μg/L (n=112) showed increased bacterial presence (25.0%) but still maintained viral predominance (64.3%). At PCT levels of 0.25-0.5 μg/L (n=98), bacterial infections became more prevalent (57.1%). The highest PCT category (>0.5 μg/L, n=151) showed the strongest correlation with bacterial infections (91.4%), with only 5.3% viral infections and 3.3% indeterminate cases. The analysis of antibiotic usage patterns and clinical outcomes by RTI type demonstrated significant variations across different respiratory conditions Table 3. CAP patients (n=193) showed the highest mean PCT levels (0.86 ± 0.42 μg/L), followed by AECOPD (0.45 ± 0.31 μg/L) and Upper RTI (0.18 ± 0.15 μg/L). PCT-guided therapy consistently reduced antibiotic duration across all RTI types compared to standard care: CAP (6.2 vs 9.1 days), AECOPD (5.4 vs 8.3 days), and Upper RTI (4.1 vs 7.2 days). Clinical cure rates remained comparable between PCT-guided and standard care approaches across all RTI types, ranging from 87.8% to 92.2%. The laboratory parameters analysis showed significant correlations between PCT levels and other inflammatory markers showed in Table 4. Patients with PCT >0.25 μg/L demonstrated significantly higher WBC counts (14.6 ± 4.8 vs 8.2 ± 3.1 ×109/L), CRP levels (96.8 ± 45.2 vs 42.3 ± 28.6 mg/L), and ESR values (68.5 ± 31.4 vs 38.4 ± 22.1 mm/hr) compared to those with PCT <0.25 μg/L. Notably, the rates of positive blood cultures (28.9% vs 4.5%) and positive sputum cultures (52.6% vs 12.4%) were substantially higher in the elevated PCT group. The multivariate analysis of factors affecting treatment success revealed several significant predictors Table 5. PCT-guided therapy

showed a positive association with treatment success (adjusted OR: 1.42, 95% CI: 1.18-1.72, p=0.002), as did early antibiotic initiation (adjusted OR: 1.56, 95% CI: 1.28-1.90, p<0.001). Negative predictors included age >65 years (adjusted OR: 0.78, 95% CI: 0.62-0.98, p=0.035), CURB-65 score ≥3 (adjusted OR: 0.65, 95% CI: 0.48-0.88, p=0.006), and initial PCT >0.5 μg/L (adjusted OR: 0.71, 95% CI: 0.56-0.90, p=0.004). The presence of diabetes showed a non-significant trend toward poorer outcomes (adjusted OR: 0.82, 95% CI: 0.64-1.05, p=0.112).

Table 1: Demographic and Clinical Characteristics of Study Population (N=450)

Characteristic	PCT-guided group (n=225)	Standard care group (n=225)	P-value
Age (years)*	58.4 ± 15.2	57.9 ± 14.8	0.72
Male gender, n(%)	128 (56.9)	132 (58.7)	0.69
Type of RTI			
CAP, n(%)	98 (43.6)	95 (42.2)	0.78
AECOPD, n(%)	76 (33.8)	79 (35.1)	0.76
Upper RTI, n(%)	51 (22.6)	51 (22.7)	0.99
Comorbidities			
Diabetes	67 (29.8)	64 (28.4)	0.75
Hypertension	89 (39.6)	92 (40.9)	0.77
Heart disease	45 (20.0)	48 (21.3)	0.72
Clinical Severity			
CURB-65 score ≥3	42 (18.7)	44 (19.6)	0.81
qSOFA score ≥2	38 (16.9)	36 (16.0)	0.85

*Mean ± SD

Table 2: PCT Level Distribution and Clinical Outcomes

PCT Level (μg/L)	Total patients	Bacterial infection confirmed	Viral infection confirmed	Indeterminate
<0.1	89	12 (13.5%)	68 (76.4%)	9 (10.1%)
0.1-0.25	112	28 (25.0%)	72 (64.3%)	12 (10.7%)
0.25-0.5	98	56 (57.1%)	31 (31.6%)	11 (11.2%)
>0.5	151	138 (91.4%)	8 (5.3%)	5 (3.3%)

Table 3: Antibiotic Usage Patterns and Clinical Outcomes by RTI Type

Parameter	CAP (n=193)	AECOPD (n=155)	Upper RTI (n=102)	P-value
Mean PCT (μg/L)*	0.86 ± 0.42	0.45 ± 0.31	0.18 ± 0.15	<0.001
Antibiotic duration (days)*				
PCT-guided	6.2 ± 2.1	5.4 ± 2.3	4.1 ± 1.8	<0.001
Standard care	9.1 ± 2.8	8.3 ± 2.6	7.2 ± 2.4	<0.001
Clinical cure rate (%)				
PCT-guided	87.8	90.8	92.2	0.42
Standard care	86.3	89.9	91.8	0.48

*Mean ± SD

Table 4: Laboratory Parameters and PCT Correlation

Parameter	PCT <0.25 µg/L (n=201)	PCT >0.25 µg/L (n=249)	P-value
WBC (×109/L)*	8.2 ± 3.1	14.6 ± 4.8	<0.001
CRP (mg/L)*	42.3 ± 28.6	96.8 ± 45.2	<0.001
ESR (mm/hr)*	38.4 ± 22.1	68.5 ± 31.4	<0.001
Positive blood culture (%)	4.5	28.9	<0.001
Positive sputum culture (%)	12.4	52.6	<0.001

*Mean ± SD

Table 5: Multivariate Analysis of Factors Affecting Treatment Success

Variable	Adjusted OR	95% CI	P-value
PCT-guided therapy	1.42	1.18-1.72	0.002
Age >65 years	0.78	0.62-0.98	0.035
CURB-65 score ≥3	0.65	0.48-0.88	0.006
Diabetes	0.82	0.64-1.05	0.112
Initial PCT >0.5 µg/L	0.71	0.56-0.90	0.004
Early antibiotic initiation	1.56	1.28-1.90	<0.001

DISCUSSION

The study population demonstrated well-balanced baseline characteristics between the PCT-guided and standard care groups. The mean age and gender distribution were comparable to those reported in similar studies (Wilson et al., 2018; Thompson et al., 2021). The distribution of RTI types reflected the typical pattern seen in tertiary care settings, with CAP being the predominant diagnosis (43.6% vs. 42.2%), followed by AECOPD (33.8% vs. 35.1%). This distribution aligns with previous multicenter studies (Anderson et al., 2020). The comorbidity profile showed a balanced distribution of common conditions such as diabetes, hypertension, and heart disease between groups. This is particularly important as these comorbidities can influence both PCT levels and clinical outcomes, as noted by Garcia et al. (2019). The severity scores (CURB-65 and qSOFA) were also comparable between groups, ensuring a valid comparison of outcomes.

The diagnostic performance analysis of PCT levels demonstrated a robust correlation with bacterial infection confirmation across different concentration thresholds. In cases of low PCT levels (<0.1 µg/L), the study revealed a high negative predictive value of 86.5% with predominant viral etiology (76.4%) and excellent clinical outcomes achieved without antibiotic intervention. These findings strongly support the safety of withholding antibiotics at this threshold, aligning with the conclusions of Roberts et al. (2021) regarding PCT-guided antibiotic stewardship. The intermediate PCT range (0.1-0.25 µg/L) presented a more complex clinical picture, with a moderate bacterial confirmation rate of 25.0% and significant viral presence (64.3%). This "gray zone" required careful consideration of additional clinical parameters for informed decision-making, as emphasized in the research by Harrison et al. (2018). High PCT levels (>0.5 µg/L) demonstrated the strongest diagnostic utility with a 91.4% correlation with bacterial infection and minimal viral presence (5.3%), providing a clear indication for antibiotic therapy. These findings correspond with the diagnostic accuracy metrics reported by Chen et al. (2019), supporting PCT's role as a reliable

biomarker for bacterial infection. The clear stratification of PCT levels and their corresponding clinical implications provides a robust framework for antimicrobial stewardship decision-making, though emphasizing the importance of clinical correlation, particularly in intermediate ranges.

Analysis of antibiotic usage patterns revealed significant differences between PCT-guided and standard care approaches. Across all RTI types, PCT-guided therapy led to more targeted antibiotic use, with the most pronounced effect observed in upper RTIs (mean duration reduction: 3.1 days). In CAP patients, while the antibiotic initiation rates remained high in both groups, the PCT-guided approach facilitated earlier discontinuation (6.2 vs. 9.1 days, $p<0.001$). This finding aligns with Johnson & Peters (2020), who reported similar reductions in antibiotic duration without compromising clinical outcomes. The AECOPD subgroup demonstrated particularly favorable results, with a 35% reduction in antibiotic exposure (5.4 vs. 8.3 days, $p<0.001$), supporting the findings of Davidson et al. (2019) regarding PCT-guided antibiotic optimization in COPD exacerbations.

The correlation between PCT levels and other inflammatory markers provided additional validation of the PCT-guided approach. Patients with PCT >0.25 μg/L showed significantly elevated WBC counts (14.6 ± 4.8 vs. 8.2 ± 3.1 $\times 10^9$/L, $p<0.001$) and CRP levels (96.8 ± 45.2 vs. 42.3 ± 28.6 mg/L, $p<0.001$), consistent with bacterial infection. The positive blood culture rate was markedly higher in the elevated PCT group (28.9% vs. 4.5%, $p<0.001$), supporting PCT's role as a predictor of bacteremia, as previously reported by Thompson et al. (2021). The strong correlation between PCT levels and positive microbiological cultures (blood and sputum) reinforces its utility in identifying patients most likely to benefit from antibiotic therapy.

Multivariate analysis revealed several significant predictors of treatment success. PCT-guided therapy emerged as an independent favorable factor (adjusted OR: 1.42, 95% CI: 1.18-1.72, $p=0.002$), along with early antibiotic initiation when indicated (adjusted OR: 1.56, 95% CI: 1.28-1.90, $p<0.001$). Age >65 years and higher severity scores were associated with less favorable outcomes, consistent with previous studies (Baker et al., 2019). The analysis demonstrated that PCT-guided therapy maintained its beneficial effect even after adjusting for these confounding factors. The clinical cure rates were comparable between groups across all RTI types, with slightly higher rates in the PCT-guided group for AECOPD (90.8% vs. 89.9%) and upper RTIs (92.2% vs. 91.8%), though these differences did not reach statistical significance.

The implementation of PCT-guided therapy achieved high protocol compliance (87.6%), though several challenges were noted. Initial physician resistance was overcome through regular education sessions and feedback mechanisms. The rapid availability of PCT results (median turnaround time: 2.4 hours) was crucial for effective implementation, supporting the findings of Walsh et al. (2020) regarding implementation success factors. The study observed improved protocol adherence over time, with compliance rates increasing from 82.3% in the first quarter to 91.8% in the final quarter, suggesting a learning curve effect in protocol implementation.

Safety analysis revealed no significant differences in adverse outcomes between groups. The 30-day mortality rates were comparable (3.6% vs. 4.0%, $p=0.81$), and no excess complications were observed in the PCT-guided group. Subgroup analysis of high-risk patients (CURB-65 ≥ 3) showed similar safety profiles, though these patients had generally poorer outcomes regardless of group allocation. These findings support the safety of PCT-guided therapy across different risk

strata, consistent with the meta-analysis by Rodriguez-Baño et al. (2018).

Limitations and Recommendations

The single-center design may limit generalizability, particularly to settings with different resource availability or patient populations. The inability to blind clinicians to group allocation could have introduced bias, though the objective nature of many outcome measures helps mitigate this concern. The study's 30-day follow-up period, while standard for similar investigations, may not capture longer-term outcomes or impacts on antimicrobial resistance patterns. Future research should focus on the long-term effects of PCT-guided therapy on bacterial resistance patterns, its integration with other biomarkers and clinical decision tools, and its implementation in resource-limited settings.

CONCLUSION

The findings strongly support the integration of PCT-guided therapy into antibiotic stewardship programs for respiratory tract infections. The clear correlation between PCT levels and bacterial infection, combined with favorable clinical outcomes and reduced antibiotic exposure, provides a compelling argument for widespread implementation. However, successful adoption requires careful consideration of local resources, establishment of clear protocols, and ongoing education of healthcare providers. The study's results suggest that PCT-guided therapy can significantly contribute to antimicrobial stewardship efforts while maintaining patient safety, particularly when implemented as part of a comprehensive clinical assessment approach.

CONFLICTS OF INTEREST
None

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AUTHORS CONTRIBUTION
All authors have equal contribution.

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